

Translation

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PCT/JP2003/010181

PATENT COOPERATION TREATY



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference K04F1073	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/010181	International filing date (day/month/year) 08 August 2003 (08.08.2003)	Priority date (day/month/year) 12 August 2002 (12.08.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/198, 9/20, 47/10, 47/26, 47/36, 47/38		
Applicant KYOWA HAKKO KOGYO CO., LTD.		

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 6 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

- This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand 19 February 2004 (19.02.2004)	Date of completion of this report 05 August 2004 (05.08.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/010181

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.
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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	11	YES
	Claims	1-10, 12-17	NO
Inventive step (IS)	Claims		YES
	Claims	1-17	NO
Industrial applicability (IA)	Claims	1-17	YES
	Claims		NO

2. Citations and explanations

The inventions that are set forth in claims 1-10 and 12-17 lack novelty in the light of documents 1 and 2 cited in the international search report. The chewable tablets set forth in claims 1 and 7, which contain an amino acid and a carboxymethyl cellulose (calcium), are disclosed in document 1 (paragraphs [0004], [0007] and [0035]) and document 2 (claim 1 and paragraphs [0018] and [0020]).

The invention that is set forth in claim 11 is not disclosed in any of the documents that are cited in the international search report; therefore, it is novel. Specifically, chewable tablets that contain valine, leucine or isoleucine are not disclosed in any of the documents.

However, the invention that is set forth in claim 11 does not involve an inventive step in the light of documents 1-4 cited in the international search report. A person skilled in the art could easily conceive of using valine, leucine or isoleucine, as disclosed in documents 3-4, in the place of the amino acids that are disclosed in documents 1-2.

Document 1: JP 2000-007555 A

Document 2: JP 2000-095707 A

Document 3: JP 2002-003372 A

Document 4: JP 2001-169752 A

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1 and 2 pertain to chewable tablets that are specified by means of a desired property; namely, an "improved disintegration property in the oral cavity" or a "rapid disintegration property in the oral cavity." Claims 1 and 2 include all chewable tablets that exhibit such properties; however, only a small portion of the claimed chewable tablets are disclosed in the meaning of PCT Article 5, and the chewable tablets are not considered to be fully supported by the disclosures of the description in the meaning of PCT Article 6.

Even with consideration of common technical knowledge at the time the present application was filed, it is impossible to specify the scope of the chewable tablets that can serve as a "chewable tablet that exhibits an improved disintegration property in the oral cavity" or a "chewable tablet that exhibits a rapid disintegration property in the oral cavity." Therefore, claims 1 and 2 do not comply with the requirement of clarity as defined in PCT Article 6.

Claims 3-6 and 8-17 pertain to chewable tablets containing a compound that is specified by means of a desired property; namely, "promoting disintegration in the oral cavity." Claims 3-6 and 8-17 include all compounds that exhibit such a property; however, only a small portion of the claimed compounds are disclosed in the meaning of PCT Article 5, and the compounds are not considered to be fully supported by the disclosures of the description in the meaning of PCT Article 6.

Even with consideration of common technical knowledge at the time the present application was filed, it is impossible to specify the scope of the compounds

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VIII. Certain observations on the international application

that can serve as a "component for promoting disintegration in the oral cavity." Therefore, claims 3-6 and 8-17 do not comply with the requirement of clarity as defined in PCT Article 6.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
JP 2003-221327 A	05 August 2003 (05.08.2003)	25 January 2002 (25.01.2002)	25 January 2002 (25.01.2002)

[E, X]

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)Date of written disclosure
referring to non-written disclosure
(day/month/year)